IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094**
	:	**24-md-3094**
THIS DOCUMENT RELATES TO:	:	
ALL ACTIONS/ALL CASES	:	

DEFENDANTS NOVO NORDISK AND ELI LILLY'S RESPONSE TO PLAINTIFFS' POSITION STATEMENT

Plaintiffs' Position Statement underscores the importance of reliable science and effective case management tools to position this MDL for an efficient and fair resolution.

First, whether GLP-1RA medicines are capable of causing and did cause Plaintiffs' alleged injuries (*i.e.*, general and specific causation) will be critical gating issues. Plaintiffs assert that GLP-1RA medicines cause gastroparesis, ileus, and intestinal blockage, ECF No. 87, at 6-9, but they cite ***no study*** showing that semaglutide (Ozempic®, Wegovy®, and Rybelsus®), tirzepatide (Mounjaro®), or dulaglutide (Trulicity®) significantly increase the risks of any of these conditions. Their references instead illustrate the problems they will face proving causation. For example, Plaintiffs cite the website for the National Institutes of Health's ("NIH's") National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"). *Id.* at 7. But that publication does not mention GLP-1RAs at all; instead, it states that "[d]iabetes is the most common known underlying cause of gastroparesis,"[1] and that "[y]ou are more likely to get gastroparesis if you . . . have diabetes."[2] This is significant because Ozempic®, Mounjaro®, and Trulicity® are approved to treat diabetes. Thus, the number one risk factor for gastroparesis pre-existed in many Plaintiffs before taking any GLP-1RA medicine. Plaintiffs also cite a study involving intestinal obstruction (Sodhi 2023, n.24), but that study did not assess tirzepatide or dulaglutide for any injury, and it reported *zero* intestinal obstruction cases in patients treated with semaglutide.[3]

Second, the warnings to and knowledge of healthcare providers about potential side effects will be cross-cutting issues. Plaintiffs' Position Statement does not claim doctors (to whom any

[1] NIH, NIDDK, *Symptoms & Causes of Gastroparesis*, https://tinyurl.com/4szbzrh7.
[2] NIH, NIDDK, *Definition & Facts for Gastroparesis*, https://tinyurl.com/2k6xb2d3.
[3] Mohit Sodhi et al., *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, 330 JAMA 1795 (2023) (Table 1), https://tinyurl.com/ytdhr2tt. That study also has been criticized for its limitations. *See, e.g.*, Karine Suissa et al., *GLP-1 Receptor Agonists and Gastrointestinal Adverse Events*, 331 JAMA 884 (2024), https://tinyurl.com/2er392s6.

duty to warn runs under the learned intermediary doctrine) were unaware of risks of gastrointestinal side effects arising from GLP-1RA use; in fact, they have been common knowledge in the medical community for years. These risks are prominently discussed in the FDA-approved product labeling, *see* ECF Nos. 85-1 to -3, and have been discussed for years in treatment guidelines, textbooks, reference sources, and websites, *e.g.*:

- "The most common side effects of GLP-1 Ras are nausea, vomiting, and diarrhea . . . GI side effects generally diminish with continued use. Contraindications include gastroparesis and severe renal disease."[4]

- "GLP-1 reduces gastrointestinal motility [and] has a pronounced effect on gastric emptying of both liquid and solid meals . . . . The most common adverse events observed in clinical trials with GLP-1Ras involve the gastrointestinal system, mainly nausea, vomiting, and diarrhea, and these events diminish over time."[5]

Such widespread knowledge within the medical community will be important here because a plaintiff cannot prove a failure-to-warn claim where her physician had notice of the alleged risk.

Third, Plaintiffs' Position Statement highlights the need to address the scope and definition of alleged injuries at Science Day to categorize and efficiently manage the cases. While the complaints generally fall in four buckets of claims (ECF No. 85, at 1-2), Plaintiffs discuss only two of those injuries—gastroparesis and ileus/intestinal obstruction—and state they "anticipate that the most commonly alleged injuries will be gastroparesis or bowel obstruction." ECF No. 87, at 6-7. Plaintiffs do not address gallbladder injuries or non-specific gastrointestinal symptoms, even though such claims make up nearly 50% of filed cases (12% gallbladder and 34% nonspecific, all Novo only).

Fourth, Plaintiffs' claims about the scope and variability of injuries emphasize the need for

[4] Larry Jameson et al., *Endocrinology: Adult & Pediatric E-Book* 847 (2015), https://tinyurl.com/yvrpd3fn.
[5] Allan Flyvbjerg, *Textbook of Diabetes* 458, 464 (2017), https://tinyurl.com/5n8b8ufe.

early case management tools. Plaintiffs say that "injuries alleged in this MDL cover a wide spectrum in terms of severity," ranging from those that "resolve after a brief hospitalization and treatment including drugs or surgery" to those that develop into "irreversible, secondary conditions." *Id.* at 6. This is precisely why a robust PFS process is so important and supports the need for overall inventory reports (for filed and unfiled cases) at status conferences, so the Parties can accurately categorize and efficiently litigate and resolve the claims in this MDL.

Fifth, the NIH website Plaintiffs cite amplifies the importance of diagnosis based on objective confirmatory testing to identify which Plaintiffs have gastroparesis. The NIH reports that, while "[g]astroparesis is not common," "*symptoms that are similar to those of gastroparesis occur in about 1 out of 4 adults in the United States*."[6] These symptoms include feelings of fullness after eating, nausea, vomiting, and heartburn.[7] As explained in Defendants' Position Statement, these overlapping and ubiquitous gastrointestinal symptoms are precisely why clinical symptoms alone are not sufficient to reliably diagnose or support gastroparesis claims. ECF No. 85, at 6-8.

Finally, Plaintiffs' marketing claims cannot obscure their warning and causation problems. They devote much of their Position Statement (4 of 14 pages) to critiques of alleged "marketing conduct" or off-label promotion. But this MDL is about whether Defendants "failed to adequately warn" of potential gastrointestinal side effects, ECF No. 87, at 13, not about marketing allegations unconnected to the elements of their claims. Nor do any of Plaintiffs' marketing allegations support their ancillary claims, to the extent they are asserting them against any Defendant.

Moreover, Novo and Lilly will demonstrate that their respective marketing and other public statements encouraged responsible use of their medicines, consistent with their approved labels

[6] NIH, NIDDK, *supra* n.2 (emphasis added).
[7] NIH, NIDDK, *supra* n.1.

and indications, and only through prescription and close consultation with a healthcare provider. For example, Novo Nordisk maintains a website (semaglutide.com) dedicated specifically to the responsible use of semaglutide, which includes a wide range of information for physicians and patients. The website emphasizes that semaglutide medicines should "only be used for appropriate patients consistent with their FDA-approved label" and not for "cosmetic weight loss," warns about the risks associated with unapproved counterfeit and compounded drugs (none of which are associated with Novo), discusses the role of telehealth providers, and reminds patients that semaglutide medicines should "only be prescribed after a close consultation between a healthcare provider and a patient . . . and should only be taken under the supervision of a healthcare provider.[8]

Lilly issued an Open Letter Regarding the Use of Mounjaro® and Zepbound® which reiterated that these medicines "are not approved for—and should not be used for—cosmetic weight loss," and are not approved for use in children, and voiced its concern about safety risks when patients use compounded or counterfeit medicines.[9] And while Plaintiffs criticize efforts to raise obesity awareness (ECF No. 87, at 11-13), this archaic position disregards the profound clinical consequence of obesity recognized by countless authorities on public health, including the U.S. Surgeon General, American Medical Association, and World Health Organization.[10]

Plaintiffs' Position Statement underscores why the Court should adopt case management tools to narrow and focus the litigation, deter meritless claims, and categorize claims for omnibus

[8] *Novo Nordisk Is Committed to the Responsible Use of Our Medicines*, https://tinyurl.com/esasuzem; novoMEDLINK, *Responsible Use Letter*, https://tinyurl.com/mry5z8bp.
[9] *See* Lilly, Open Letter Regarding the Use of Mounjaro® (tirzepatide) and Zepbound® (tirzepatide), https://tinyurl.com/4swcwsfy.
[10] HHS, *Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity* (2001), https://tinyurl.com/4ruewbc4; Am. Med. Ass'n, *AMA Adopts Policy to Help Physicians, Students Prevent, Manage Obesity* (2017), https://tinyurl.com/yrpyn4cn; WHO, World Obesity Day 2021, https://tinyurl.com/44kvwj5w.

resolution through cross-cutting motion practice. These threshold steps will ensure proportionate discovery, representative bellwether selection, and the efficient and fair resolution of this litigation.

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Respectfully Submitted,

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